

REMARKS

This responds to the Office Action dated 30 July 2009. Claims 1, 12, 20 and 28 are amended above. Support for the amendments to the claims is provided by at least FIG. 1B and the related description of that figure in the present application. No new matter has been added. Claims 31-37 were withdrawn previously. Therefore, claims 1-30 remain pending in the application.

Claim Rejections - 35 U.S.C. § 103

Claims 1 and 12-14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,545,178 to Kensey et al. in view of U.S. Patent No. 3,976,079 to Samuels et al. Applicant respectfully traverses this rejection.

Claim 1 as amended recites "the ratchet mechanism including a first member that maintains a fixed position relative to the filament, and a second member that is movable along the filament relative to the first member and configured to apply a pressure to the sealing plug to form a seal between the tissue wall puncture and the sealing plug." Claim 12 as amended recites "the ratchet mechanism including a first member that maintains a fixed position relative to the internal component, and a second member that is movable relative to the internal component and configured to apply a pressure to the external component to form a seal between the lumen and the external component." Claim 20 as amended recites "the ratchet mechanism including a first member that maintains a fixed position relative to the anchor, and a second member that is movable relative to the first member to compress the sealing plug toward the anchor to seal the

puncture.” Claim 28 as amended recites “the strap and hub comprise a ratchet mechanism configured to apply a pressure to the sealing plug to compress the sealing plug along the strap toward the anchor to form a seal between the tissue wall puncture and the sealing plug.”

Kensey discloses with reference to FIGS. 1-5 a device 20 used to seal closed a tissue puncture. The device 20 includes a sealing member 36, an anchoring member 38, a holding member 40, and a positioning filament 42 that interconnects the features 36, 38, 40. The holding member 40 is constructed as a disc that slides along the filament 42 to compress the sealing member 36 toward the anchoring member 38 (*see* FIGS. 6 and 7). The holding member 40 is a single piece device that is void of a ratchet mechanism. Furthermore, the holding device 40 moves in its entirety toward the anchor along the filament 42 to compress the sealing member 36.

There is no disclosure or suggestion by Kensey of combining the holding member 40 with any other feature to assist in compressing the sealing member 36 or of maintaining the sealing member 36 in a compressed state.

Samuels discloses with reference to FIGS. 12-13 a device 70 that includes a body having a slot 76 through which a suture 102 extends. A ratchet tab 80 is manually operable to pivot about a connection point on the body to contact and lock the suture 102 in a first position (*see* FIG. 13), and to be removed from contact with the suture in a second position (*see* FIG. 14). A ratchet tab 80 includes a plurality of ratchet teeth 86. When the ratchet tab 80 is in the locked position, the entire device 70 is fixed relative to the suture 102 to prevent suture 102 from moving relative to device 70 in

either axial direction. When the ratchet tab 80 is in the unlocked position, the entire device 80 is movable along the suture 102 in either axial direction.

Samuels fails to disclose or suggest a ratchet mechanism that includes "a first member that maintains a fixed position relative to the filament, and a second member that is movable along the filament relative to the first member" as required by claim 1. The device 70 disclosed by Samuels moves as a complete unit along the suture 102 or is fixed as an entire unit relative to the suture. .

Samuels also fails to disclose or suggest "the ratchet mechanism including a first member that maintains a fixed position relative to the internal component, and a second member that is movable relative to the internal component," as required by claim 12 for at least the same reasons discussed above related to claim 1. If the device 70 disclosed by Samuels were combined with the Kensey device, no part of the device 70 of Samuels would be fixed relative to an internal component, such as the anchoring member 38, while another portion of the device 70 would be movable relative to the anchoring member 38.

In view of the above, Applicant submits that Kensey and Samuels, alone or in combination, fail to disclose or render obvious every limitation of claims 1 and 12 and the claims that depend from them.

Claims 2-11 and 15-30 stand rejected as being unpatentable over Kensey in view of Samuels and further in view of U.S. Published Application No. 2003/0176890 to Buckman et al. Applicant respectfully traverses this rejection.

Kensey and Samuels fail to disclose or render obvious every limitation of claims 1 and 12 for at least those reasons discussed above. Buckman fails to remedy the

deficiencies of Kensey and Samuels as they relate to claims 1 and 12. Therefore, Applicant submits that claims 2-11 and 15-19 are allowable for at least the reason they are dependent upon an allowable base claim. Applicant does not otherwise concede the correctness of this rejection as it relates to claims 2-11 and 15-19.

Kensey fails to disclose or suggest a ratchet mechanism that includes first and second members (*see* claim 20) or a strap and hub that comprises a ratchet mechanism configured to "compress the sealing plug along the strap toward the anchor" (*see* claim 28) for at least those reasons discussed above related to claims 1 and 12.

Samuels fails to disclose or suggest "the ratchet mechanism including a first member that maintains a fixed position relative to the anchor, and a second member that is movable relative to the first member to compress the sealing plug toward the anchor," as required by claim 20. If the Samuels device were used in place of the holding member 40 on the Kensey device, as suggested by the Examiner, the entire Samuels device 70, including the ratchet tab 80, would be movable relative to the anchoring member 38 to compress the sealing member 36. Therefore, Samuels fails to disclose or suggest every limitation of claim 20.

Samuels, like Kensey, also fails to disclose "a ratchet mechanism" that compresses "the sealing plug along the strap toward the anchor." The features of Samuels identified as a ratchet mechanism by the Examiner do not compress the sealing plug along a strap. There is no suggestion or motivation provided by Samuels or Kensey to use the devices disclosed by either of those references with another device such as a strap to "compress the sealing plug."

Buckman discloses a device 10 having serrations 20 on both ends 18 and a pressure plate 26 having a ratcheting lock 28 with a plurality of locking tabs 32. Operation of the ratcheting lock 28 and the serrations 20 provides one-way movement of the pressure plate 26.

The rejection contends that the ratchet mechanism disclosed by Buckman is functionally equivalent to the locking mechanism taught in Samuels and therefore would be an obvious combination. Applicant respectfully disagrees. The devices taught by Samuels and Buckman are fundamentally different both in structure and function. The Samuels device is constructed as a device that is intended to move along a suture freely until a ratchet tab 80 is manually rotated into contact with the suture, thus locking the entire device from moving in either axial direction along the suture. The entire device is again able to move axially in either direction upon manually releasing the ratchet tab 80 from contacting the suture.

In contrast, the Buckman device includes a ratcheting lock 28 that provides free movement of the pressure plate 26 in one direction while automatically preventing movement in the opposite direction. The Buckman device is automatic in operation while the Samuels device is manually operated. Furthermore, there is no disclosure or suggestion within Buckman of using the device with a suture, which is fundamental to operation of the Samuels device.

Further to the above, there is no teaching or suggestion by Kensey, in particular related to the structure, operation, and purpose of the holding member 40 that would suggest to one of ordinary skill in the art to replace the holding member 40 with an alternative mechanism that includes moving parts such as the manually actuated ratchet

tab 80 of Samuels or the ratcheting lock 28 of Buckman, which is functional only in combination with a bolt having a plurality of serrations rather than for use with a suture.

In view of the above, Applicant submits that there is no disclosure or suggestion by Kensey that would lead one of ordinary skill in the art to combine the Samuels or Buckman references. Furthermore, there is no disclosure or suggestion by either Kensey or Samuels that would motivate one of skill in the art to replace the Samuels locking device, which includes a manually operated ratchet tab 80, with the ratcheting lock disclosed by Buckman. In fact, the purpose and function of the Samuels device (*i.e.*, lock the entire device 70 relative to a suture or release the entire device to move freely along the length of the suture) teaches away from the structure and function of the Buckman device.

In view of the above, Applicant submits that Kensey, Samuels, and Buckman, alone or in combination, fail to disclose or render obvious "the ratchet mechanism including a first member that maintains a fixed position relative to the anchor, and a second member that is movable relative to the first member to compress the sealing plug towards the anchor," as required by claim 20, and "the strap and hub comprise a ratchet mechanism configured to apply pressure to the sealing plug to compress the sealing plug along the strap towards the anchor to form a seal between the tissue wall puncture and the sealing plug," as required by claim 28. Therefore, Applicant submits that Kensey, Samuels, and Buckman fail to disclose or render obvious every limitation of claims 20 and 28 and the claims that depend from them.

Conclusion

For at least the foregoing reasons, Applicant believes that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicant respectfully requests a favorable action on the merits. If the Examiner has any further comments or suggestions, Applicant invites the Examiner to telephone the undersigned attorney to expedite the handling of this matter.

Applicant expressly disclaims all arguments, representations, and/or amendments presented or contained in any other patent or patent application, including any patents or patent applications claimed for priority purposes by the present application or any patents or patent applications that claim priority to this patent application. Moreover, all arguments, representations, and/or amendments presented or contained in the present patent application are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application.

Respectfully submitted,

Date:

28 October 2009



L. Grant Foster
Registration No. 33,236